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10/642,591

08/19/2003

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EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

06/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/642,591 | Applicant(s) ISSHIKI ET AL. | |
| | Examiner JING OU | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the amendment filed on 03/22/2010. Claims 1 and 3-16 are pending. Claim 1 is independent. Claim 2 is cancelled. Claims 12-16 are newly added.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 4, 7, 11-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US Pub. No.: 2003/0144685) in view of Khosravi (US Pat. No.: 6,361,546) and Brooks et al (US Pat. No.: 6,346,116).

In regard to Claims 1, 3, 4, 7, 11-13, and 16, Boyle et al discloses a sheath; a flexible shaft being a wire member that serves as a guide wire; a thrombus capture member having a proximal end and a distal end; said capture member comprise a cross wire member and a filter attached thereto, said filter being provided with pores and

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being mounted on the distal side of said crossed wire member, said crossed wire member being fixed at the proximal end thereof to said shaft and being slidably mounted at the distal end on said shaft, said shaft passing through the thrombus capture member and protruding from the distal end of the thrombus capture member; wherein said thrombus capture member is further provided at the distal end thereof with a sliding ring assembly comprising an inner ring and an outer ring, the wire of said crossed wire member being sandwiched between and fixed to said inner and outer rings at the distal end of said thrombus capture member, said inner ring being slidably mounted on the shaft.

Boyle et al does not appear to disclose a closing member attached the sheath, said crossed wire member comprising a plurality of spirally configured wires, and the pore size of the filter

However, Khosravi teaches a closing member attached to the proximal end of the sheath. It would have been obvious to make the Boyle et al thrombus capture catheter to include a closing member attached to the proximal end of the sheath as taught by Khosravi to provide a handle for the surgeon to grip onto to manipulate the sheath. Applicant should be noted that it is old and well known to use hemostatic valves and tubular members to hold the valves in surgical devices in order to obtain the advantage of preventing blood loss. It would have been obvious to include a hemostatic valve and tubular member in the Boyle et al device so that it too would have this advantage. In addition, Khosravi teaches that the pore size of a filter is at least about 0.05-0.3mm. Applicant should be noted that the pore size of a filter is merely an

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obvious design choice and within one of ordinary skill in the art. Furthermore, Brooks et al. teach that filter frame wires 56 comprising a plurality of spirally-configured wires (Fig. 4), said wires being arranged around a shaft by surrounding the shaft spirally and by allowing the wires to cross each other (Fig. 4 and col. 4, lines 37-43) apparently in order to obtain the advantage of better supporting the filter membrane around its circumference. It would have been obvious to make the Boyle et al filter frame wires 24 spiral and crossed with one another so that it too would have this advantage.

Furthermore, the spirally-configured wires are tapered in a substantially equal manner at the proximal and distal ends thereof (Fig. 3). Applicant should be noted that the number of spirally-configured wires is merely an obvious design choice and within one of ordinary skill in the art.

5. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US Pub. No.: 2003/0144685) in view of Khosravi (US Pat. No.: 6,361,546) and Brooks et al (US Pat. No.: 6,346,116) as applied to claim 1 above, and further in view of Rosenbluth (WO 99/56801). As to claim 5, Boyle et al in view of Khosravi and Brooks et al discloses all the limitations as taught above but fails to disclose a side hole and second lumen in the sheath. However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side hole 310 and second lumen 309 in order to obtain the advantage of permitting rapid exchange of the sheath (page 18, lines 13-22). It would have been obvious to include a side hole and second lumen in the Khosravi sheath so that it too would have this advantage. As to claim 6, Khosravi fails to disclose a side infusion tube. However, Rosenbluth teaches that a sheath 11 for an

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intravascular filter should include a side infusion port 15 attached thereto in order to obtain the advantage of permitting injection of contrast medium into the vessel (page 15, lines 15-24). It would have been obvious to include a side infusion port in the Khosravi device so that it too would have this advantage.

6. Claims 8-10, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US Pub. No.: 2003/0144685) in view of Khosravi (US Pat. No.: 6,361,546) and Brooks et al (US Pat. No.: 6,346,116) as applied to claim 1 above, and further in view of Borillo et al (US Pub No.: 2003/0060844).

In regard to Claims 8, 14, and 15, Boyle et al in view of Khosravi and Brooks et al discloses all the limitations as taught above but fails to disclose the proximal end of the thrombus member is fixed to the shaft by a fixed ring comprising an inner ring and an outer ring. However, Borillo et al discloses that the proximal end of the thrombus member is fixed to the shaft by a fixed ring (704, Para. [0075]) comprising an inner ring and an outer ring (inner ring and outer ring are shown in Fig. 9. The wire member are sandwiched between the inner ring and outer ring). At the time of the invention was made, it would have been obvious to modify the Boyle et al device to include a fixed ring comprising an inner ring and an outer ring for securing the proximal end of the thrombus member to the shaft to obtain the advantage of providing a strong attachment between the wires and ring assembly. It would have been obvious to so construct the sliding ring in the Boyle et al device so that it too would have this advantage.

In regard to claims 9 and 10, Boyle et al in view of Khosravi and Brooks et al discloses all the limitations of the claim as taught above and further discloses that the

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filter is a funnel-shaped member including a constringent part and a constricted part extending from the smaller end of the constringent part, said constringent part being provided with plural pores and that the thrombus capture member is slidably attached the distal end thereof to the shaft by a slide ring and fixed at the proximal end thereof to the shaft by a fixed ring (col. 4, lines 24-27 and Fig. 1-2B). Boyle et al in view of Khosravi and Brooks et al does not appear to disclose a cylindrical part. However, Borillo et al teaches a filter comprising a cylindrical part (Fig. 14A). The motivation/suggestion for doing so would have been served as a superstructure to which the filter and the struts of the strut assembly can be adhesively or otherwise affixed. In addition, the cylindrical part provides better attachment of the filter to the blood vessel since more surface area of the filter contacts the blood vessel wall. Therefore, it would have been obvious to combine Borillo et al with Boyle et al in view of Khosravi and Brooks et al to obtain the claimed invention as specified in the instant claim.

Response to Arguments

7. Applicant's arguments with respect to claims 1 and 3-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. O./

Examiner, Art Unit 3773

06/11/2010

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773